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EXAMINER

HELMER, GEORGIA L.

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/721,047

Applicant(s)

TUMER ET AL.

Examiner

Georgia L. Helmer

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 13-17, 19-31 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5, 12, 18 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Restriction election***

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No 12, filed 26 November 2002. Applicant elects Group I, (b), claims 1-12, 18-24 and 32, directed to recombinant plant cells and PAPII (1-285), which is SEQ ID NO: 3, with traverse. Applicant traverses, saying primarily that the various components of Groups I, II, and III, are not unrelated, and that previous patents to Applicant involving similar components and groupings have not been restricted by the PTO. Applicant's traversal has been considered and is unpersuasive because groups I-III are properly restricted as described in the restriction requirement. Furthermore, the facts of each case are different.
2. Claims 1-37 are pending. Claims 1-5, 12, 18, and 32 are examined in the instant Action. Claims 6-11, 13-17, 19-31 and 33-37 are withdrawn as being drawn to nonelected inventions. The claim dependency of claim 32, drawn to a vector, as being dependent on claim 25, drawn to a protein, is in error; the Office assumes claim 25 to depend on claim 18, drawn to a DNA molecule.
3. This restriction is made FINAL.

***Information Disclosure Statement***

4. An initialed and dated copy of Applicant's IDS forms 1449, Paper No 6, filed 24 May 2001, is attached to the instant Office action.

***Claim Rejections - 35 USC § 112-second***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 4, 5, 12 and 18 are rejected under 35 U.S.C. 112-2<sup>nd</sup>.

Claim 1 recites a sequence encoding a "PAPII protein". Applicant says (p 7) that "PAPII protein" also includes mutants or analogues of the wild-type polypeptide such as fragments and amino acid substitutions and /or deletions. Defined this way, PAPII protein is indefinite; it can means many different things and is unclear because the metes and bounds of such a claim cannot be defined.

Claims 1, is drawn to a recombinant plant cell or plant thereof containing a DNA molecule comprising a sequence encoding a PAP II protein, but there is no recitation of a transformation with a heterologous sequence. Therefore it is unclear what this plant cell is. It can be a Pytolacca Americana cell. Dependent claims 2, 4, 5, and 12, are also rejected.

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In claim 4, the recited "PAPII (1-285)" needs a SEQ ID NO: inserted into the claims as an identifier.

In claim 5, a "mutant" PAPII is unclear because the metes and bounds of such a claim cannot be defined. A "mutant" can encompass deletions, substitutions, additions, rearrangements, replacements, and combinations thereof.

Claims 5 and 18, reciting an "intact" catalytic active site amino acid residue, are unclear. What is "intact"? The active site? The amino acid residue? Or something else.

In claims 4, 5, and 18, the meaning of the numbers in parentheses is unclear. Are these terms further clarification or are they limitations?

The claim dependency of claim 32 as being dependent on claim 25 is in error; the Office assumes claim 25 to depend on claim 18.

Clarification and/or correction are required.

***Claim Rejections - 35 USC § 112, first paragraph***

***Written description***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1-5, 12, 18, and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a recombinant plant cell or part thereof containing a DNA molecule comprising a sequence encoding a PAP II protein. Applicant says (p 7) that "PAPII protein" also includes mutants or analogues of the wild-type polypeptide such as fragments and amino acid substitutions and /or deletions. There is no structural description, of what comprises the PAP II protein, and there is no functional requirement or description. Applicants are claiming a genus of sequences, yet there is no description of the structural features or the functional features that define the genus.

Claim 5 is drawn to a recombinant plant cell containing a DNA molecule comprising a sequence encoding a PAP II protein, where in the sequence encodes a "mutant PAPII protein that has intact catalytic active site amino acid residue (E172) and exhibits anti-viral and/or anti-fungal activity. There is no structural description, other than the intact E172, of what comprises the mutant PapII. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

Claim 18 is drawn to a DNA molecule comprising a sequence encoding a PAP II protein, where in the sequence encodes a PAPII protein that has intact catalytic active site amino acid residue (E172) and exhibits anti-viral and/or anti-fungal activity. There is no structural description, other than the intact E172, of what comprises the Pap II.

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Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . . Accordingly, the specification does not provide a written description of the invention . . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111.)

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 18 and 32 are rejected under 35 U.S.C. 102 (b) as anticipated by Poyet, et al, FEBS Letters, Vol 347, pages 268-272, 1994.

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Poyet teaches a DNA molecule (p 269, Figure 1) comprising a sequence encoding a PAPII protein (p 269, Figure 1) that has intact catalytic active site amino acid residue (E172) and exhibits anti-viral and/or anti-fungal activity (p268 paragraph 2). Poyet further teaches a vector comprising this DNA molecule (p 269, section 2.2 and 2.3).

Because of the lack of clarity of the term "intact" catalytic active site amino acid residue, this term is given no patentable weight.

Accordingly, Poyet anticipates the claimed invention.

### Remarks

11. SEQ ID NO: 3 is known in the prior art.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

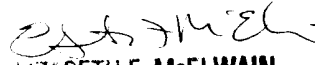
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Group 1638  
February 7, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800